



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9-18951
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 23, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Reference: Warning Letter SEA 02-05
Inspection ID: 1641940007

Angie Wilkerson, Assistant Radiology Manager
Breast Care Center Sedro-Woolley
1971 Highway 20
PO Box 410
Sedro-Woolley, WA 98284

WARNING LETTER

Dear Ms. Wilkerson:

We are writing to you because on October 11, 2001, your facility was inspected by Bill Van Pelt, a representative of the State of Washington, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat level two finding:

Failure to produce documents verifying that the interpreting physician, [REDACTED] M.D., met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

Ms. Angie Wilkerson, Assistant Radiology Manager
Breast Care Center Sedro-Woolley, Sedro-Woolley, WA
Warning Letter SEA 02-05

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It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

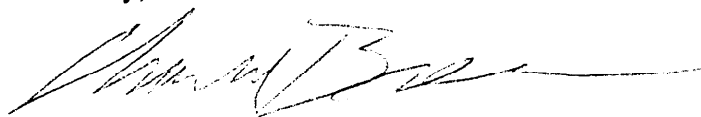
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: patient names or identification should be deleted from any copies submitted).*

Please submit your response to U.S. Food & Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law.

You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.

Ms. Angie Wilkerson, Assistant Radiology Manager
Breast Care Center Sedro-Woolley, Sedro-Woolley, WA
Warning Letter SEA 02-05

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CC:
Priscilla F. Butler, M.S.
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Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Bill Van Pelt
Washington State Radiation Control
2409 E. Valley Street
Seattle, WA 98112